IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS INC., and ONYX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and MYLAN INC.

Defendants.

C.A. No. ____________________

COMPLAINT

Plaintiffs Bayer HealthCare LLC ("BHC"), Bayer HealthCare Pharmaceuticals Inc. ("BHCPI") (BHC and BHCPI are collectively referred to herein as "Bayer") and Onyx Pharmaceuticals, Inc. ("Onyx") (Bayer and Onyx are collectively referred to herein as "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant Mylan Pharmaceuticals Inc. of Abbreviated New Drug Application ("ANDA") No. 207012 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' NEXAVAR® product prior to the expiration of U.S. Patent Nos. 8,618,141 and 8,877,933. As set forth in its FDA-approved labeling, NEXAVAR® is indicated for the treatment of certain types of cancer.

THE PARTIES

2. Plaintiff Bayer HealthCare LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey.

3. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey.

4. Plaintiff Onyx Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 249 E. Grand Avenue, South San Francisco, California.

5. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, and is registered to do business in Delaware, having designated its registered agent as Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware.

6. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania.

7. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc. and is controlled and dominated by Mylan Inc. On information and belief, Mylan Pharmaceuticals Inc. develops and manufactures numerous generic drugs for sale and use throughout the United States at the direction of, under the control of, and for the direct benefit of Mylan Inc.

8. On information and belief, Defendant Mylan Pharmaceuticals Inc. is actively registered with the Delaware Board of Pharmacy, pursuant to Del. C. § 2540, as a licensed "Pharmacy-Wholesale Drug Distributor" (License No. A4-0001719) and "Distributor/Manufacturer CSR" (License No. DM-00007571).

9. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. share common employees, officers and/or directors.

10. On information and belief, Mylan Pharmaceuticals Inc.'s preparation and submission of ANDA No. 207012 for Mylan Pharmaceutical Inc.'s sorafenib tosylate tablets, 200 mg ("Mylan's ANDA Product") was done at the direction of, under the control of, and for the direct benefit of Mylan Inc.

11. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. are agents of each other, and/or operate in concert as integrated parts of Mylan's business, including with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into Delaware, of generic pharmaceuticals, including the infringing Mylan ANDA Product at issue.

12. On information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 207012, Mylan Pharmaceuticals Inc. and Mylan Inc. will act in concert to distribute and sell Mylan's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Mylan" or "Defendants." On information and belief, following any FDA approval of ANDA No. 207012, Mylan knows and intends that its ANDA Product will be distributed and sold in the United States and within Delaware.

JURISDICTION AND VENUE

13. Plaintiffs incorporate paragraphs 5 through 12 as if each fully set forth herein.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over the defendants.

16. The Court has personal jurisdiction over Defendants because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to BHC, a Delaware limited liability company; BHCPI, a Delaware corporation; and Onyx, a Delaware corporation. For example, Mylan Pharmaceuticals Inc. sent the Notice Letter (defined below) to BHC, which has led and/or will lead to foreseeable harm and injury to BHC in Delaware.

17. Mylan Pharmaceuticals Inc. consented to jurisdiction in Delaware by registering to do business in Delaware and appointing a Delaware agent to accept service of process.

18. On information and belief, Defendants will manufacture, market, and/or sell within the United States the generic product described in ANDA No. 207012 if FDA approval is granted. If ANDA No. 207012 is approved, the generic product accused of infringement would, among other things, be marketed and distributed in Delaware, prescribed by

physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

19. Mylan Pharmaceuticals Inc. and Mylan Inc. have been frequent litigants in this District in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending the Notice Letter to BHC, a Delaware limited liability company, BHC would file suit in this jurisdiction.

20. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

21. NEXAVAR® (active ingredient sorafenib tosylate) is a kinase inhibitor indicated for the treatment of unresectable hepatocellular carcinoma, advanced renal cell carcinoma, and locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

22. BHCPI is the holder of New Drug Application No. 21923 for NEXAVAR®, which has been approved by the FDA.

The '141 Patent

23. United States Patent No. 8,618,141 (the "'141 patent"), entitled "Aryl Ureas With Angiogenesis Inhibiting Activity", was duly and legally issued on December 31, 2013. The '141 patent is attached as Exhibit A.

24. As set forth in greater detail in the '141 patent, the claims of the '141 patent, incorporated by reference herein, cover, *inter alia*, methods of blocking angiogenesis in a tumor of the kidney comprising administering to a human or other mammal with a tumor of the kidney an effective amount of sorafenib tosylate.

25. BHC is the assignee of the '141 patent.

26. Onyx is an exclusive licensee under the '141 patent.

27. Pursuant to 21 U.S.C. § 355, the '141 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NEXAVAR®.

28. The expiration date of the '141 patent is February 11, 2023.

29. By letter dated December 19, 2014 (the "Notice Letter"), Mylan notified BHC that Mylan had submitted to the FDA ANDA No. 207012 for Mylan's ANDA Product. This product is a generic version of NEXAVAR®.

30. In the Notice Letter, Mylan stated that Mylan's ANDA Product contains sorafenib tosylate.

31. On information and belief, the proposed labeling for Mylan's ANDA Product directs the use of Mylan's ANDA Product for the treatment of advanced renal cell carcinoma.

32. On information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for Mylan's ANDA Product will infringe one or more claims of the '141 patent.

33. In the Notice Letter, Mylan notified Plaintiffs that, in connection with its ANDA No. 207012, Mylan Pharmaceuticals Inc. had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications"), with respect to the '141 patent.

34. The purpose of ANDA No. 207012 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product with its proposed labeling prior to the expiration of the '141 patent.

35. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '141 patent.

36. Mylan's Notice Letter did not provide a valid basis for concluding that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling would not infringe at least one valid and enforceable claim of the '141 patent.

37. Mylan has knowledge of the claims of the '141 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012.

38. Mylan plans and intends to, and will, actively induce infringement of the '141 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. The foregoing actions by Mylan constitute and/or will constitute infringement of the '141 patent and/or active inducement of infringement of the '141 patent.

40. Mylan is without a reasonable basis for believing that it will not be liable for infringing the '141 patent and/or actively inducing infringement of the '141 patent.

41. An actual case or controversy exists between Plaintiffs and Mylan with respect to infringement of the '141 patent.

The '933 Patent

42. United States Patent No. 8,877,933 (the "'933 patent"), entitled "Thermodynamically Stable Form Of A Tosylate Salt", was duly and legally issued on November 4, 2014. The '933 patent is attached as Exhibit B.

43. BHC is the assignee of the '933 patent.

44. As set forth in greater detail in the '933 patent, the claims of the '933 patent, incorporated by reference herein, cover sorafenib tosylate in the polymorph I form and pharmaceutical compositions containing sorafenib tosylate in the polymorph I form. As set forth in greater detail in the '933 patent, the claims of the '933 patent also cover methods of manufacturing sorafenib tosylate in the polymorph I form and methods of using sorafenib tosylate in the polymorph I form.

45. Onyx is an exclusive licensee under the '933 patent.

46. Pursuant to 21 U.S.C. § 355, the '933 patent is listed in the Orange Book in connection with NEXAVAR®.

47. The expiration date of the '933 patent is December 24, 2027.

48. In the Notice Letter, Mylan stated that Mylan's ANDA Product contains sorafenib tosylate.

49. On information and belief, Mylan's ANDA Product contains sorafenib tosylate in the polymorph I form.

50. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product, including the use of Mylan's ANDA Product in accordance with and as directed by Mylan's labeling for that product, will infringe one or more claims of the '933 patent.

51. The purpose of ANDA No. 207012 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product prior to the expiration of the '141 patent; accordingly, because the '933 patent expires later than the '141 patent, the purpose of ANDA No. 207012 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product prior to the expiration of the '933 patent.

52. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '933 patent.

53. On information and belief, Mylan has knowledge of the claims of the '933 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to expiration of the '933 patent.

54. On information and belief Mylan plans and intends to, and will, actively induce infringement of the '933 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

55. On information and belief, Mylan knows that Mylan's ANDA Product is especially made or adapted for use in infringing the '933 patent, and that Mylan's ANDA Product is not suitable for substantial noninfringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the '933 patent immediately and imminently upon approval of ANDA No. 207012.

56. On information and belief, the foregoing actions by Mylan constitute and/or will constitute infringement of the ’933 patent, active inducement of infringement of the ’933 patent, and/or contribution to the infringement by others of the ’933 patent.

57. On information and belief, Mylan is without a reasonable basis for believing that it will not be liable for infringing the ’933 patent, actively inducing infringement of the ’933 patent, and/or contributing to the infringement by others of the ’933 patent.

58. An actual case or controversy exists between Plaintiffs and Mylan with respect to infringement of the ’933 patent.

COUNT I
(Infringement of the ’141 Patent)

59. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

60. Mylan’s submission of ANDA No. 207012 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan’s ANDA Product is an act of infringement of the ’141 patent under 35 U.S.C. § 271(e)(2).

61. Unless Mylan is enjoined from infringing the ’141 patent and actively inducing infringement of the ’141 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Declaratory Judgment as to the ’141 Patent)

62. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

63. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

64. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Product with its proposed labeling prior to the expiration of the '141 patent.

65. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '141 patent.

66. On information and belief, pursuant to 35 U.S.C. § 271(a) and/or (b), Mylan's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Mylan's ANDA Product with its proposed labeling would constitute infringement of the '141 patent and/or inducement of infringement of the '141 patent.

67. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 207012 will infringe one or more claims of the '141 patent.

68. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling infringes and actively induces the infringement of the '141 patent.

COUNT III
(Infringement of the '933 Patent)

69. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

70. Mylan's submission of ANDA No. 207012 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product is an act of infringement of the '933 patent under 35 U.S.C. § 271(e)(2).

71. Unless Mylan is enjoined from infringing the '933 patent, actively inducing infringement of the '933 patent, and contributing to the infringement by others of the '933 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV
(Declaratory Judgment as to the '933 Patent)

72. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

73. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

74. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Product prior to the expiration of the '933 patent.

75. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '933 patent.

76. On information and belief, pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g), Mylan's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Mylan's ANDA Product, including in accordance with its proposed labeling, would constitute infringement of the '933 patent, inducement of infringement of the '933 patent, and contribution to the infringement of the '933 patent.

77. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product according to ANDA No. 207012 will infringe one or more claims of the '933 patent.

78. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product infringes, actively induces the infringement of, and contributes to the infringement by others of the '933 patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Mylan has infringed the '141 patent;

(b) A judgment that Mylan has infringed the '933 patent;

(c) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan's ANDA Product, or any product or compound the use of which infringes the '141 patent, be not earlier than the expiration date of the '141 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan's ANDA Product, or any product or compound which infringes or the use of which infringes the '933 patent, be not earlier than the expiration date of the '933 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, form making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound the use of which infringes the '141 patent, or the inducement of any of the foregoing, prior to the expiration date of the '141 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, form making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '933 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '933 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound the use of which infringes the '141 patent, prior to the expiration date of the '141 patent, will infringe and actively induce infringement of the '141 patent;

(h) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '933 patent, prior to the expiration date of the '933 patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the '933 patent;

(i) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(j) An award of Plaintiffs' costs and expense in this action; and

(k) Such further and other relief as this Court may deem just and proper.

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January 30, 2015